Evaluation of a Clinical Trial as a Teletrial Checklist

Insert subtitle

*Use this checklist to guide the decision making about whether a clinical trial is suitable to be conducted under the teletrials model. This evaluation may be undertaken with the site feasibility for new trials (with a confirmed protocol), or as needed if considering introducing Satellite Sites (with identified potential participants) into an already running clinical trial.*

*This form may also be submitted to the Sponsor when seeking approval to have the trial conducted under the teletrials model.*

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| **Clinical Trial Title** |  |
| **Sponsor Type** | Delete whichever is not relevant.Commercial / Collaborative Group / Institution |
| **Sponsor Name** |  |
| **Sponsor Representative** |  |
| **Contact details for Sponsor Representative** | **T:****E:** |
| **Site Name** |  |
| **Principal Investigator** |  |
| **Site Contact Person** |  |
| **Contact details for site** | **T:****E:** |

| **Pharmacy and Investigational Medicinal Product (IMP)** |
| --- |
| Is IMP supplied per participant for the entire study at the outset? Or is it sent in batches throughout the study? |  |
| Can IMP be easily transported to the site?  | e.g. Is cold chain transport required with temperature data loggers etc  |
| Is IMP to be assigned via a pharmacy portal? If yes, when can this be assigned? For example, can IMP only be assigned on the day of the clinic visit or can IMP be assigned a week in advance to ensure adequate time for delivery from the primary site? |  |
| Will IMP be sent to the Primary Site only or will the Sponsor also send IMP to Satellite Sites? | CTN implications |
| Who meets these costs? |  |
| How will IMP get to satellite sites during extreme weather events such as floods? | e.g. RFDS agrees to take a box of IP on routine visit, for collection by research staff. |
| Who will dispense IMP?  |  |
| Where will the IMP be stored and what are the storage requirements? | Will Sponsor agree to store IP at Satellite Sites? (CTN implications). |
| Does the IMP have preparation requirements?  | e.g. shelf life after reconstitution; storage requirements, sterile prep?  |
| If IMP requires reconstitution, who can do this? | e.g. Site staff, Site Pharmacy, External provider |
| How is the IMP administered? | Delete whichever is not relevant.Oral / Parenteral / Other |
| Who will administer the IMP? |  |
| Is special equipment required to administer IMP or other study medication? | e.g. specific giving sets |
| If special equipment is required to administer IMP, who supplies the equipment? Sponsor or site? |  |
| Is special training required to site staff to administer IMP? | If yes, who will provide this training? |
| Does the dose vary throughout the trial or is the same dose given throughout? |  |
| If doses vary, what are they based on and is there a sufficient visit window to allow for dispensing of new IMP? |  |
| Who is responsible for the accountability log?  |  |
| What are the identified adverse events and suspected unexpected serious adverse reactions for the IMP? |  |
| What are the requirements or instructions for the destruction of the IMP?  |  |
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| **Pathology** |
| Are specimens processed locally or through a Central Laboratory? | All processing locally / Basic processing locally / Central Lab |
| Are there specific pathology processing requirements? If necessary, liaise with the relevant jurisdictional manager for regional pathology laboratories. The laboratory manual for the trial may be required. | e.g. specific centrifuge process, time specific processing, -80oC freezer. If there is an issue sourcing a vital item of equipment, please contact the SA/NT RCCC team |
| If additional training for processing specimens is required, who provides this training? |  |
| If dry ice is required, who provides this? |  |
| Are there specific specimen transport requirements? | Will specimens be held & sent in batches, or sent on the day of the study visit? |
| Will Sponsor pay costs associated with transporting specimens from Satellite Sites? |  |
| If the protocol requires specimens to be stored at -80oC, will the sponsor agree to allow these to be stored at -20oC in the short term, until shipped to the Primary site for longer storage or batch shipping? Or can it be stored at -20oC until shipped directly to the central lab in the next day or week? |  |
| Who will be responsible for handling/shipping? (includes dry ice)If research team is responsible, is the shipper certified appropriately? | Local lab / Research teamYes / (No: Please contact SA/NT RCCC team) |
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| **Imaging** |
| Is there complex and specific imaging required for this clinical trial? Is there an imaging protocol for the study? | e.g. echocardiograms, MRI, PET Scans etc? |
| If so, are the scanners or other required imaging equipment available in rural and remote areas? |  |
| Are there other specific requirements such as no software upgrades during the conduct of the study? |  |
| Is there an uploading requirement for the imaging? What is the data file transfer platform? |  |
| Are there specific training requirements for imaging? |  |
| Are sites required to pass qualification testing for imaging? |  |
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| **Trial Design and Study Visits** |
| Does the trial design allow for some or all visits to be undertaken via telehealth at a Satellite Site?(Please consider both treatment and non-treatment visits) |  |
| What telehealth technologies/facilities are available at site? | e.g Healthdirect |
| Are there specific visits or procedures that must be done at the Primary Site? |  |
| Will the Sponsor contribute to participant travel costs from Satellite Sites to Primary Site? |  |
| Are there additional investigations or tests not mentioned above that are required in this clinical trial? (Please note if these are part of Standard of Care, or additional assessments specifically for the trial) | e.g. Cardiopulmonary Exercise tests (CPET), specific respiratory function tests  |
| Is there specific testing or measuring equipment required for this clinical trial eg cognitive testing kits, Intravascular Ultrasound, sponsor provided 12 lead ECG machines? |  |
| If specialist equipment IS required for this clinical trial, is it available at all potential Satellite Sites or will additional equipment need to be sourced for Satellite sites?(Please note here if the Sponsor agrees to provide additional equipment) | If there is an issue sourcing a vital item of equipment, please contact the SA/NT RCCC team |
| How will monitoring be undertaken?  |  |
| Does the Sponsor accept electronic signatures? |  |
| Where will Satellite Site study documentation be stored during the trial? At the Satellite Site or sent to the Primary Site?  |  |
| Who is responsible for archival? Occasionally sponsors prefer to organise archival themselves, or expect you to and will at times reimburse you to do so |  |
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| **Regulatory** |
| What contract is intended to be used for this trial? | Delete whichever is not relevant (indemnity implications).MA CTRA Std; MA CTRA CRO; MA CTRA CRG; MTAA CIRA; Other (please specify). |
| Who will provide indemnity to any potential Satellite Sites? | Sponsor / Site Institution / Other (please specify).(If Primary & Satellite Site/s are one institution then Primary Site’s Indemnity may cover both – please check) |
| Will the Sponsor provide Investigator Site File to Satellite Sites or will Primary Site have the only ISF and Satellite Sites have a subset of documents? |  |
| Will this trial be conducted under the CTN / CTA scheme? |  |
| Where will study documentation from Satellite Sites be archived at the end of the study and for how long? |  |
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| **Other Comments** |
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| **Date of checklist completion** |
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If there are items that you consider should be included in this document, please let us know.
E: sarccc@sa.gov.au or nthealth.teletrials@nt.gov.au

*If it is decided that this trial is not suitable to be conducted under the teletrials model, please send this completed form to the SA/NT Regional Clinical Trials Coordinating Centre (SA/NT RCCC), along with any additional information about why the trial was not suitable, as it will assist in analysis and reporting of the success of the Teletrials model.*

*If the trial appears suitable to be conducted under the teletrials model, but the Sponsor chooses not to allow this, please also send this form, along with the Sponsor’s rationale, to the SA/NT RCCC as it will assist us in identifying barriers and obstruction in implementing this model.*

Email SA: sarccc@sa.gov.au

Email NT: nthealth.teletrials@nt.gov.au